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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,450	12/05/2003	Christina Khoo	7129-00	1031

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EXAMINER	
FORD, ALLISON M	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
02/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/729,450	KHOO ET AL.	
	Examiner	Art Unit	
	ALLISON M. FORD	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19 and 26-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19 and 26-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/21/2008 has been entered.

Claims 19, 27 and 28 have been amended; claims 1-18 and 20-25 are cancelled; no new claims were added. Claims 19 and 26-28 are currently pending in the application, all of which have been considered on the merits.

Response to Arguments/Amendments

Applicants' remarks filed 11/21/2008 have been fully considered, and will each be addressed below, as appropriate. Rejections/objections not repeated herein have been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19 and 26-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 now requires the diet to include from about 30 to about 50 ug/g ascorbic acid.

First, the measurement unit "ug/g" is unclear, is it micrograms per gram of *diet?* Micrograms per gram of *other antioxidants?* Clarification is required.

Second, ascorbic acid is vitamin C, which is also categorized as an antioxidant and is specifically claimed as a species of antioxidant in claim 27. It is unclear if the 'about 30 to about 50 ug/g of ascorbic acid' is in addition to the 0.1% to about 3% antioxidants required by the composition, or if the 'about 30 to about 50 ug/g' is part of the 0.1 to 3%.

Claim 28 is held as indefinite because it appears to be broader than claim 19, and thus fails to properly correlate with the parent claim.

Claim 19 has been amended to require the diet to additionally comprise ascorbic acid, omega-6 fatty acid and crude fat; thus it would appear that each of the recited ingredients are necessary for effectively treating IBD. However, claim 28 appears to state that only the combination of glutamine, fermentable fiber, antioxidants, and omega-3-fatty acids in the diet are necessary for effective treatment of watery, runny stool and soft unformed stool (which are the symptoms of IBD). Therefore, it appears claim 28 is broader than claim 19, as the method of claim 28 requires less ingredients to be present in the fed diet. Clarification and/or correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

In response to the rejections of record under 35 USC 103(a), Applicants submit that the amendments overcome the rejections of record.

In response, it remains that Applicants have provided no evidence or persuasive reasoning as to why their method, involving administration of a diet composition comprising common and well known ingredients, wherein each ingredient is known for general nutrition (i.e. fats, fiber, omega fatty acids, antioxidants), or was known specifically to improve gastrointestinal health (i.e., glutamine), is nonobvious over the teachings of the art. Wherein the differences lie only in the recited concentrations of the various ingredients, it remains that, absent persuasive evidence showing unexpected results achieved with the claimed concentrations, optimization and modification of the concentrations of each ingredient would have been routinely carried out by the artisan of ordinary skill, and thus do not serve to patentably distinguish the current invention over the prior art. The following rejections are set forth to address the new claim limitations:

Claims 19 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shields, Jr. et al (US Patent 6,156,355), in view of Wadsworth et al (US Patent 6,737,089) and Klimberg et al (*Arch Surg*, 1990), further in view of Taber's Cyclopedic Medical Dictionary (1997).

Shields, Jr. et al teach a dog food composition, 'The Herding Diet' which comprises fermentable fibers, in the amount of 4.0%; omega-6 fatty acids, in the amount of 2.75% (which is considered to read on "about 1.5% by weight); omega-3 fatty acids, in the amount of 0.2%; crude fat, in an amount of 10% (which is considered to read on "about 4% to about 6% by weight); antioxidants; and glutamine (See Shields, Jr. et al, col. 9, ln 48-51; col. 11, ln 25-38 & 53-54; col. 12, ln 11-15; col. 23, ln 4-14 & 'Analysis'). The antioxidants included in the diet comprise tocopherols (vitamin E) and vitamin C (ascorbic acid) (See Shields, Jr. et al, col. 5, ln 44-48). The 'Herding Diet' is specially formulated for dogs that are prone to chronic GI inflammation and diarrhea; it is designed to be fed to dogs as a means of controlling GI inflammation and diarrhea (See Shields, Jr. et al, col. 11, ln 18-28). Shields, Jr. et al teach

that the glutamine is the primary source of fuel for the cells for the intestinal tract, and it is beneficial in stress situations (such as times of gastrointestinal stress), in particular it is beneficial to cells of the immune system of the intestinal tract (See Shields, Jr. et al, col. 12, ln 11-22); however, they do not disclose a precise amount of glutamine to include in the diet.

Regarding the amount of glutamine to be included in the diet composition, it is submitted that the claimed amount of glutamine would have been obvious to one of ordinary skill in the art, at the time the invention was made, based on the disclosure of Wadsworth et al and Klimberg et al. Wadsworth et al and Klimberg et al both provide similar teachings on the benefits of glutamine on intestinal health during times of gastrointestinal stress. It is submitted that diarrhea is a sign of diminished gastrointestinal health (See Taber's Cyclopedic Medical Dictionary, 1997). Wadsworth et al teach glutamine, 5-10% wt, as an additive to animals' diets, specifically dog and cat diets, can provide improved digestive system support (See Wadsworth et al, col. 7, ln 51-60 and col. 13, ln 34-49 (Example 4)). Klimberg et al teach adding glutamine, 3% wt, to diets of rats suffering gastrointestinal distress from abdominal radiation, resulted in diminished bloody diarrhea and reduced the incidence of bowel perforation (See Klimberg et al, Pg 1040, col. 2- Pg. 1041, col. 2). Therefore, it would therefore have been obvious to the person of ordinary skill in the art at the time the invention was made to use the amounts of glutamine specified by either Wadsworth et al or Klimberg et al (5-10% and 3%, respectively) in the diet disclosed by Shields, Jr. et al. Shields, Jr. et al already teach using glutamine in the 'Herding Diet' in order to treat stressed GI tracts, however because they do not teach a specific amount of glutamine, one of ordinary skill in the art would have been motivated to use the amounts of glutamine taught by Wadsworth et al and Klimberg et al. One would expect success because all three teach that glutamine treats stressed GI tracts by providing the essential fuel for intestinal immune cells.

Regarding the amount of antioxidants to be included in the diet composition, it is submitted that the claimed amount of antioxidants, including vitamin C, would have been obvious to one of ordinary

skill in the art, at the time the invention was made, based on the disclosure of Wadsworth et al. While Shields, Jr. et al does teach the importance of antioxidants as scavengers of oxygen, and terminators of free radicals (col. 5, ln 65- col. 6, ln 11), they do not teach a specific amount of antioxidants present in the diet. However, Wadsworth et al also teach inclusion of vitamins and antioxidants, such as vitamins A, C and E, and disclose the desired amount as being from 0-10% by weight (See Wadsworth et al, col. 5, ln 24-42). However, any pharmaceutical amount would be appropriate for these diets. Excess vitamins are flushed from the system; therefore, it would be obvious to include any amount of antioxidants, within a pharmaceutically accepted range, with expectations of the benefits and without concern of over dosage. Therefore, though Shields, Jr et al is silent on the amount of antioxidants in their diet, it would have been obvious to include any amount within a pharmaceutical range, such as 0.1-3% by weight total, and/or 30-50 ug/g ascorbic acid (Vitamin C).

Finally, while it is noted that the composition of Shields, Jr et al, and its use in methods of managing gastrointestinal disorders, such as diarrhea, is limited to dogs, whereas Klimberg et al's experiments are conducted on rats, and Wadsworth et al's teachings are directed to both dogs and cats, it is submitted that the teachings of Klimberg et al and Wadsworth et al would have been recognized as extendable to dogs, as described by Shields, Jr et al. This statement is based on the fact that each of rats, cats and dogs are mammals having simple digestive tracts, and it is known that glutamine has similar beneficial effects on all three species (as disclosed by the individual references). For the same reasons it would be obvious to extend the results of Shields, Jr. et al, in view of Klimberg et al and Wadsworth et al, to cats; therefore, a diet of the same composition, including glutamine, fermentable fiber, omega-3 fatty acids, and antioxidants in the specified amounts, and use of such composition for the treatment of diarrhea, including diarrhea caused by intestinal bowel disease, would have been obvious for use in dogs as well as non-canine mammals, such as cats.

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 19 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler (*In Practice,* 2002).

Chandler teaches diets for dogs and cats for the treatment and control of gastrointestinal diseases, which result in symptoms such as diarrhea. Chandler et al teach that a diet, which includes fermentable fibers, omega-3 fatty acids, antioxidants, particularly water soluble vitamins C (ascorbic acid) and B (See Pg. 531), and glutamine, can benefit an animal with a stressed gastrointestinal tract (See Chandler, Pg. 529, col. 2, and especially Pg. 533, col. 1). Chandler disclose fat levels in the diet should be approximately 12-22%; however fat levels of >10% are common in low calorie diets (See Chandler, paragraph spanning pages 530-531); these values, especially >10% fat is considered to read on "about 4 to 6% crude fat". The omega-3 fatty acids may be provided as fish oils; it is submitted that fish oils also contain omega-6 fatty acids, thus the diet also comprises omega-6 fatty acids. Chandler teaches a diet comprising these ingredients can be used as a treatment for gastrointestinal diseases (See Chandler, especially Pg. 533). It is noted that inflammatory bowel disease is a gastrointestinal disease that also results in symptoms such as diarrhea; therefore, despite the cause of the diarrhea, the diet recommended by Chandler would have the same effect on the symptoms of diarrhea.

Though Chandler is silent on the precise amounts of glutamine, fermentable fibers, omega fatty acids, and antioxidants, including vitamin C (ascorbic acid), it would have been obvious to a person of ordinary skill in the art to experiment with varying amounts, within pharmaceutical ranges, of each ingredient to optimize the treatment potential of the diet. Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical or produces unexpected results. Where the general

conditions of a claim are disclosed by the prior art it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Chandler teach that each specific ingredient plays an important role in maintaining and, in times of stress restoring gastrointestinal health (See Chandler, especially, Pg. 529, col. 1- Pg. 531, col. 1). A person of ordinary skill in the art would have been motivated to increase the amount of fermentable fiber, omega fatty acids, and antioxidants, including vitamin C, and to include glutamine in a diet for a dog or cat with GI tract problems because these ingredients are highly digestible, the fiber promotes fecal bulk, the omega fatty acids help to decrease inflammation, antioxidants promote immune response and need to be replaced during bouts of diarrhea due to being flushed out, particularly water soluble vitamins such as vitamin C, and glutamine has been found to provide energy for enterocytes during times of stress, boosting immune ability and GI health (See Chandler, Pg. 529, col. 2- Pg. 533, col. 1). One would have expected success because Chandler describes a diet containing these ingredients as a means for treating GI problems, including diarrhea caused by inflammatory bowel disease (See Chandler, Pg. 529, col. 2- Pg. 533, col. 1). Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALLISON M. FORD whose telephone number is (571)272-2936. The examiner can normally be reached on 8:00-6 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Allison M. Ford/
Examiner, Art Unit 1651